LOWER LIMB ARTERIES ASSESSED WITH DOPPLER ANGIOGRAPHY – A PROSPECTIVE COMPARATIVE STUDY WITH MULTI DETECTOR CT ANGIOGRAPHY

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CERTIFICATE

This is to certify that **Dr. K. Anu Maithrayee** has been a post graduate student during the period May 2007 to March 2010 at Barnard Institute of Radiology, Madras Medical College, Government General Hospital, Chennai.

This Dissertation titled **" Lower Limb Arteries Assessed With Doppler Angiography – A Prospective Comparative Study With Multi Detector CT Angiography"** is a bonafide work done by her during the study period and is being submitted to the Tamilnadu Dr. M.G.R. Medical University in partial fulfillment of the M.D. Branch VIII Radiodiagnosis Examination

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CONTENTS

INTRODUCTION

Lower limb arterial disease is an important cause of morbidity in middle aged and the elderly. It is commonly caused by the atheromatous narrowing or occlusion of an artery or arteries of the leg. It may be symptomatic causing intermittent claudication, ischaemic rest pain, ulceration, and gangrene[1].

Management strategies differ for patients with lower limb arterial disease. Patients with intermittent claudication are often managed conservatively, while patients with limb threatening ischemia are treated with angioplasty, surgical revascularisation or amputation[2]. The choice of intervention is governed by the severity of the disease and may involve combined treatments. Thus patients with limb threatening ischaemia require a detailed assessment for a suitable treatment plan to be developed.

Intra-arterial contrast angiography is regarded as the reference standard for investigating lowerlimb arterial disease. Its drawbacks are those associated with arterial puncture, ionising radiation and potential nephrotoxicity of iodinated contrast agents. Several alternative imaging techniques are available, including Magnetic Resonance Angiography, Computed Tomography Angiography and Duplex Ultrasonography.

While Computed Tomography Angiography carries risks relating to ionising radiation and both contrast enhanced Magnetic Resonance Angiography and

Computed Tomography Angiography carry risks associated with the use of contrast agents,[3] Duplex Ultrasonography is unassociated with any risk.

Recent advances in Duplex Ultrasound like better post-processing capability, transducer technology, image resolution, signal strength and spectral analysis capabilities have improved its ability to visualize and grade abnormalities, thus extending the scope for non-invasive assessment of peripheral arterial disease.

Several studies validate contrast material–enhanced Multi Detector CT Angiography as a noninvasive alternative to conventional Digital Substraction Angiography for imaging the vascular tree.[4-11]

Unfortunately there is a paucity of high quality trials to determine the accuracy of Magnetic Resonance Angiography (MRA), Duplex ultrasound and Computed Tomography Angiography (CTA) in the investigation of peripheral arterial disease.[1]

AIM OF THE STUDY

This prospective study aims to determine the accuracy of Duplex Ultrasound compared with MDCT angiography in identifying and estimating the degree of obstructive arterial lesions in lower limbs.

PERIPHERAL ARTERIAL DISEASE

ANATOMY OF LOWER LIMB ARTERIAL SYSTEM (Fig 1)

Aorta divides into common iliac arteries at the level of L4. Common iliac artery bifurcates at the level of L5-S1 disc into internal and external iliac artery. Internal iliac artery courses anterior and adjacent to the sacroiliac joint. External iliac artery passes obliquely down medial border of psoas & anterior and lateral to external iliac vein and becomes the common femoral artery as it passes below the inguinal ligament.

Common femoral artery is approximately 4 cm in length and divides into superficial femoral & profunda femoris arteries. Superficial Femoral Artery lies between femoral vein & nerve in femoral triangle. At the distal apex of femoral triangle, above the knee, it passes through the opening in adductor magnus to enter popliteal space as popliteal artery.

Popliteal artery after providing genicular arteries at level of knee joint passes deep to soleus , where it transverses through another fibrous tunnel.

Popliteal artery then sends paired sural arteries to gastrocnemius & soleus and ends by dividing into Anterior Tibial artery, Posterior Tibial Artery and Peroneal artery. At the level of ankle – Anterior Tibial Artery becomes Dorsalis Pedis, Posterior Tibial Artery becomes medial and lateral plantar arteries.

PERIPHERAL ARTERIAL DISEASE

Peripheral arterial disease is an important cause of morbidity in middle aged adults and the elderly. Lower limb arterial pathology may be occlusive or non occlusive (Table 1). The most common condition affecting the arteries of lower extremity is ischemia due to occlusive disease. Occlusive disease may be acute, acute on chronic or chronic. Most common cause of occlusion is atherosclerosis. Less common causes are thrombo embolism, acute thrombotic occlusion, micro embolism, trauma and vasculitis. Non Occlusive Pathology includes Aneurysm, pseudo aneurysm, AV Malformation and AV Fistula.

CLINICAL FEATURES

The clinical effect of occlusive disease varies depending on the location, severity and number of arterial lesions present. Patients may be asymptomatic, symptomatic based on which the disease is commonly divided in the Fontaine stages, introduced by Dr René Fontaine in 1954[12]

* Stage I - asymptomatic
* Stage II - intermittent claudication
* Stage III - rest pain / nocturnal pain
* Stage IV - necrosis / gangrene

TABLE 1 **Causes of occlusive arterial lesions in lower extremity arteries potentially causing claudication**

Atherosclerosis (PAD)
Arteritis
Congenital and acquired coarctation of aorta
Endofibrosis of the external iliac artery (iliac artery syndrome in cyclists)
Fibromuscular dysplasia
Peripheral emboli
Popliteal aneurysm (with secondary thromboembolism)
Adventitial cyst of the popliteal artery
Popliteal entrapment
Primary vascular tumors
Pseudoxanthoma elasticum
Remote trauma or irradiation injury
Takayasu's disease
Thromboangiitis obliterans (Buerger's disease)
Thrombosis of a persistent sciatic artery

MANAGEMENT

The management of the PAD is decided based on the Fontaine stage

* Stage 1 : Medical management - modification of risk factors which also decides cardiovascular risk and prevention of disease progression and major complications

* Stage 2 : These patients are not treated with invasive procedure unless claudication distance is very short or the symptoms limit their life style

* Stage 3 and 4 : must be treated by angioplasty / stenting / surgery

INDICATIONS FOR IMAGING

The decision to image is a decision to intervene if a suitable lesion is identified and thus is only applicable to patients with rest pain and trophic changes and to a minority of patients with intermittent claudication. Imaging is also needed in the small group of patients in whom there is a discrepancy between the history and objective clinical signs to differentiate atherosclerotic PAD from other causes such as neurogenic claudication and entrapment.

The purpose of imaging is to assess the anatomical location, morphology and extent of disease in order to determine suitability for intervention.

MANAGEMENT OF PERIPHERAL ARTERIAL DISEASE

REF: TASC II Inter-Society Consensus on Peripheral Arterial Diseases

IMAGING MODALITIES

The options for imaging are as follows:

a. Digital Subtraction Angiography (DSA)

b. Duplex Ultrasound

c. Magnetic Resonance Angiography (MRA)

d. Computed Tomography Angiography (CTA)

a. DIGITAL SUBTRACTION ARTERIOGRAPHY

DSA is still considered the gold standard against which other techniques are compared[39]. Digital cine-flouroscopy allows real-time guidance of interventional procedures which are first-line management for critical ischemia, especially in patients who are not fit for a general anesthesia. Modern angiography suites consist of ultra-rapid digital cine-fluoroscopy systems, mounted on C-arms, with digital display facilities and complex post-processing software. The most critical step is the computerized subtraction of the precontrast (mask) image from the post-contrast image, producing a resultant image of contrast-filled vessels only.

Digital subtraction techniques reduce the dose of contrast required. Good spatial and temporal resolution, combined with a large field of view, allows bolus chasing from the aorta to the feet. The peripheral arterial tree can be seen and mapped quickly with overlapping runs. Large numbers of collaterals can be anatomically visualized quickly and in one session. More recently, rotational computed angiography (Dyna-CT) has been introduced. This involves a modified angiography image intensifier, with a rotating C-arm, so that computed tomography-like slices can be acquired in the interventional suite.

Advantages

* used to guide endovascular intervention

* provides a complete arterial map of the lower limb circulation which is easily interpretable.

* Pressure gradients can be measured to determine hemodynamic significance.

Limitations

* Complications of catheterisation which may occur both within the vessel and at the puncture site. Although it has been estimated that 1.7% of complications may be severe, improvements in catheter and guidewire technology have reduced their incidence significantly.[13]

* DSA involves ionizing radiation (for both patients and staff).

* The mask projections are easily distorted by patient movement, although modern software systems compensate for some motion artefacts.

* It may overestimate the length of occlusions

* It may not always demonstrate patent crural vessels.

* Slow flow can be missed depending on technical parameters (contrast injection rate, projection, or frame rate).

* Allergic reactions to iodinated contrast occur, with around 0.1% of these being severe.[14]

* There is a risk of nephrotoxicity from iodinated contrast and this is increased in elderly patients, infants, and those with pre-existing renal impairment.

b. DUPLEX ULTRASOUND

Duplex scanning combines both B-mode ultrasound and colour doppler ultrasound to provide both anatomical and hemodynamic (functional) information. Recent advances in gray scale imaging including compounding, speckle reduction techniques gives excellent high resolution images.

Advantages

* widely available
* inexpensive
* noninvasive
* nonionizing
* does not require nephrotoxic contrast.

Limitations[16]

* Operator-dependent limitations

* Operator independent limitations

- Ultrasound is a focal imaging tool, and cannot define co- existent extrinsic pathology completely or provide global imaging of the cardiovascular system.

- It cannot provide reliable imaging if there are poor acoustic windows (eg, body habitus , bowel gas attenuation, diffuse vascular calcification, or metallic stents) or poor intrinsic echogenicity of the tissues.

- Duplex scanning is time-consuming and inconvenient post-operatively – when the region of interest is obscured by dressings – and removing these can involve infection risk.

C. MAGNETIC RESONANCE ANGIOGRAPHY

Magnetic resonance angiography consists of moving-table bolus-chase protocols using gadolinium-enhancement in combination with a phased-array leg angiography coil. It is ideal for problem solving imaging of the below-knee run-off, which is not easily assessed by DU or DSA

"Hybrid" MRA is the combination of a time resolved MRA of the calf and foot followed by a bolus-chase multi station MRA. Time resolved imaging can be 2D or 3D. Hybrid MRA can detect run-off arteries not seen by DSA, which is of supreme importance in planning limb salvage surgery.[40]

Advantages

* No exposure to ionising radiation

* No risk of contrast nephropathy when gadolinium is used in recommended doses.
* Unlike uItrasound and CTA, it is unaffected by arterial calcification.

Disadvantages

* Sensitive to patient motion artefacts
* Overestimates stenosis
* Venous contamination can obscure arteries below the knee
* Claustrophobia
* Metallic implants (such as pacemakers) or foreign bodies may preclude the examination or produce magnetic susceptibility artefacts
* Gadolinium-based contrast agents has recently been associated with nephrogenic systemic fibrosis in patients with renal impairment (all cases have been in patients with a glomerular filtration rate of less than 60 ml/min).

D. COMPUTED TOMOGRAPHY ANGIOGRAPHY

The introduction of Multidetector CT scanners has dramatically improved spatial resolution and a moving tabletop enables examination from aorta to feet in a single contrast injection.

Volumetric data are then reconstructed at a workstation and normally represented in maximum intensity projection format producing easily interpretable arteriographic images.

Advantages

* Both luminal and extraluminal pathology can be shown simultaneously.

* Excellent for assessment of aneurysms and acute arterial trauma.

Limitations

* A major drawback of CT angiography is the difficulty in assessing arterial luminal stenosis in extensively calcified vessels. In the presence of extensive vessel wall calcifications, especially in small arteries, it is difficult to produce interpretable maximum intensity projection images. Overstaging – false negative stenosis or occlusion can occur because of the "blooming" effect of the calcium in calcified plaques, so that a patent vessel with calcification is mistaken for an occluded vessel on the transverse CT images.[31]

* There may be different rates of crural vessel opacification, or inadequate opacification distal to an occlusion.[28]

* CTA should be avoided in the elderly (>84 years), patients with renal failure, diabetes, or heart failure.[29]

* There is the same risk of an allergic reaction to contrast, nephrotoxicity and exposure to ionizing radiation as for DSA. Typical mean effective dose for CTA

study of the periphery (including lower limbs) has been reported as 12–14 mSv per study depending on technical protocol versus 11 mSv for DSA[17,18,19]

* Increased post-processing time

Digital subtraction arteriography is not recommended as the primary imaging modality for patients with peripheral arterial disease.

Non-invasive imaging modalities should be employed in the first instance for patients with intermittent claudication in whom intervention is being considered.[15] The comparison between various modalities is given in table 2

TABLE 2 : COMPARISON OF DIFFERENT IMAGING METHODS

Modality	Availability	Relative risk &complication	Strength	Weakness	Contraindication
Catheter angiography	widespread	Access site complications, contrast nephropathy, radiation exposure	Established modality	2D images, limited planes , imaging pedal vessels & collaterals in occlusion takes prolonged time – increased radiation exposure	Renal insufficiency contrast allergy
MDCTA	Moderate	Contrast nephropathy, radiation exposure	Rapid, 3D volumetric resolution, plaque morphology	Calcium – blooming arterfact, stented segments difficult to visualise	Renal insufficiency, contrast allergy
MRA	Moderate	none	Multiplanar, plaque morphology, no artifact from calcium	Stents – artifact (alloys- nitinol – minimal arterfact)	Intracranial devices, spinal stimulators, pacemakers, cochlear implants
Duplex	Wide spread	none	Hemodynamic Information	Operator dependant, time consuming, difficult segments difficult to assess	None

Ref: Eur J Vasc Endovasc Surg Vol 33 , supplement 1, 2007

REVIEW OF LITERATURE

Although a large number of studies were conducted in the past to evaluate the efficacy of Duplex Ultrasound in diagnosing the lowerlimb arterial disease comparing with the gold standard DSA , very few studies compares it with MDCT angiography.

Favaretto E et al[43] in 2007 studied Forty-nine patients with lower limb artery disease who underwent angiography and Duplex scanning. The sensitivity and specificity of Duplex scanning in detecting significant stenosis at angiography were calculated. They found good diagnostic agreement in the whole arterial axis. Agreement was good for the aorto-iliac segment with a sensitivity of 63% and a specificity of 96%, and for the femoro-popliteal segment with a sensitivity of 74% and a specificity of 83%. In infrapopliteal arteries, kappa showed a poor agreement, but Duplex scanning detected 28 patent tibial arteries in limbs that were not opacified on arteriography. They concluded that Duplex scanning shows good agreement with angiography in lower limb artery disease on the whole, but poor agreement in infrapopliteal segments, with a low sensitivity and high specificity in detecting significant stenoses or occlusions.

Karacagil S et al[44] from Department of Surgery, University Hospital, Uppsala, Sweden., studied 40 limbs (480 segments) with intermittent claudication (n = 6), rest pain (n = 13) and ulcer/gangrene (n = 19). Using Duplex scanning and selective angiography of femoropopliteal, crural and foot arteries. They graded each arterial segment into four categories: normal, < or = 50% diameter reduction, > 50% diameter reduction and occlusion. Pedal arteries were evaluated as patency or occlusion of dorsal pedal artery and plantar arch. Chief outcome measured were Accuracy (AC), sensitivity (SE), specificity (SP), positive predictive (PPV), negative predictive (NPV) and kappa values. They found that the Duplex scanning of the tibioperoneal trunk, crural and pedal arteries had an accuracy of 80% (kappa = 0.6). The SE, SP, PPV and NPV values were 83%, 77%, 79% and 81%, respectively. The SP was relatively low for the peroneal artery (58%) compared to the others. They concluded that the results demonstrate the feasibility and reliability of Duplex scanning in detecting crural and pedal artery lesions in lower limbs with severe ischaemia.

Krnic A et al[45] in 2006 studied 60 legs with Duplex scanning and digital subtraction angiography. The disease in each segment was assessed as significant or insignificant. They found that the duplex sensitivity in detecting significant lesions ranged from 0.46 to 0.88. The Kappa values of agreement between duplex and angiography ranged from 0.35 to 0.64. The sensitivities and specificities suggested various duplex reliabilities in detecting significant arterial disease across different lower limbs segments.

Larch E et al[46] studied Department of Medical Angiology, University of Vienna, Austria. In 1997 Fifty consecutive patients with femoropopliteal obstruction.

They concluded that sensitivity of duplex ultrasound for detecting a hemodynamically relevant arterial lesion (stenosis or occlusion) was 100% in the posterior tibial artery, 78% in the anterior tibial artery, and 92% in the peroneal artery.

Ganesh Ramaswami et al,[47] in 2006, performed duplex imaging of the iliac and femoropopliteal arteries in 125 patients undergoing angiography to determine: (1) in what percentage of patients could the iliac arteries be adequately visualized to enable a diagnosis, (2) the overall accuracy of duplex scanning in the diagnosis of arterial disease, and (3) whether there is a useful duplex criterion for the selection of patients for angioplasty. The duplex criteria of an increase in the peak systolic velocity ratio (PSVR) >2 and lesions <5 cm were used to signify hemodynamically significant stenosis (>50% narrowing), the presence of plaque and calcification in the arterial wall with alteration of PSVR and lesions >5 cm, diffuse disease, and the absence of flow on color/Doppler interrogation, occlusion. The results show that duplex scanning is a useful screening tool and may be effectively used to diagnose iliac and femoropopliteal disease in nearly 80% of patients. Angiography will be needed in those in whom duplex scanning is inconclusive, or, prior to intervention in those with disease suitable for surgical reconstruction or angioplasty, diagnosed on the basis of duplex scans.

Pinto et al [48], Department of Radiology, University of Pisa, Italy studied 334 legs in 167 consecutive patients with advanced peripheral ischemic disease using color

Doppler sonography and angiography. Colour Doppler sonography revealed diagnostic agreement with angiography in 93.5% of lesions, including 92.9% of nonsignificant stenoses, 93.9% of significant stenoses, and 95.8% of occlusions. Overestimation occurred in 7% of nonsignificant stenoses and 1% significant stenoses. Underestimation was observed in 5% of significant stenoses and in 4.2% of occlusions. Peak systolic velocity ratio correlated better ($P < 0.01$) than peak systolic velocity with diameter reduction percentage as assessed at angiography. They concluded that Color Doppler sonography is an accurate noninvasive method for evaluating patients with peripheral ischemic disease.

Chiramel George Koshy et al[49], studied 41 patients and analyzed 720 arterial segments. They found excellent concordance (1.0) in the aortoiliac segments, Good concordance in the common and external iliac segments (0.96–0.77), as well as in the common and superficial femoral segments (0.77–0.88).The popliteal segments showed lower concordance (0.66). There was only fair concordance (0.54–0.67) in the infrapopliteal segments, with relatively better results in the posterior tibial artery. The overall sensitivity ranged from 69–100%, specificity 69–100%, PPV 92–100%, and NPV from 70–100%, depending on the vascular segment evaluated. They concluded that for identifying hemodynamically significant lesions, color Doppler was found to be as good as DSA in the aortoiliac and femoropopliteal regions. However, DSA was still required to evaluate the infrapopliteal segments. They have suggested newer technologies, such as Computed Tomography Angiography and MRA, should be compared with color Doppler imaging. If larger numbers of patients are available, the performance of the imaging tests on different subgroups of patients can be assessed, particularly in those are at higher risk of adverse events (diabetes, renal insufficiency).

MATERIALS AND METHODS

STUDY POPULATION

The study group includes 34 patients with unilateral or bilateral lowerlimb ischemic disease - who have come to the department of radiology for CT angiography.

INCLUSION CRITERIA

* Age group – any age group
* Unilateral or Bilateral lowerlimb arterial disease
* Acute or Chronic lower limb arterial disease

EXCLUSION CRITERIA

* Patients with extensive ulcerations and gangrene
* Immediate unstable post operative patients with sterile dressings in lower limb
* Patients with contrast reaction
* Patients who extreme pain in the lowerlimb due to ischemia
* Patients with renal failure and contrast hypersensitivity did not undergo CT angiography

DATA ACQUISITION

DUPLEX ULTRASONOGRAPHY

* Duplex ultrasound was done with Siemens Acuson Antares Ultrasound machine band width frequency transducer with a range of 5-13MHz for lowerlimb artery and 3.5 MHz probe for infrarenal aorta and iliac vessels(Fig 2). Patients were kept fasting for at least 6 hours, to improve visualization of the aorto-iliac region
* Colour flow assisted B-mode was used to rapidly map the vessel of interest and locate lesions
* Pulse Doppler was used to analyze spectral waveform and to measure peak systolic velocity.

* Gray scale sonography to identify plaque morphological features and calcification.

Following scanner control adjustments were followed[41]

* Colour box was not too large as the image frame rate may become too low.
* The colour pulse repetition frequency was optimized so that the peak systolic velocity is in the upper region of the colour scale. Stenoses will be rapidly identified as areas of aliasing.
* The colour wall filter was set correctly.
* Angle of insonation was kept close to 60 degree to the vessel axis.

Duplex ultrasound criteria for assessment of peripheral arterial disease[22,23]

* Patency of vessel was determined by normal triphasic waveform pattern and colour saturation, demonstrated throughout the lumen of the artery(Fig 3).
* Occlusion was diagnosed, when no colour saturation and no Doppler waveform was seen in the artery(Fig 6).
* Non occlusive lesions (Fig 4,5) - Arterial lesions were located by change in colour flow pattern, change in vessel diameter and broadening of Doppler spectrum. Grading of the arterial segment with color Doppler was based on the PSV ratio and spectral pattern analysis. A hemodynamically significant stenosis (>50%) was inferred when the waveform changed from triphasic to monophasic, with appearance of spectral broadening and PSV ratio >2. Peak systolic velocity ratio is measured with respect to a point with normal flow pattern in the lumen at least 4 cm proximally. Although a number of parameters in the Doppler waveform are affected by stenoses, the peak systolic

velocity ratio is the most widely adopted measurement[32,33] . A peak systolic velocity ratio of greater than two indicates a stenosis of greater than 50%.

In order to eliminate interobserver variation, all Doppler studies were done by the same radiologist

CT ANGIOGRAPHY

CT angiography was done with PHILIPS 64 slice Multi detector CT (Fig 7) . Patients were placed in supine position with feet entering the gantry first(Fig 8). Scanogram and plain study are taken. Spiral acquisitions were performed in a single scanning pass from the level of the diaphragm down to the ankles . The average length of scanning for a patient is about 1500mm. Patients were asked to hold their breath during the first part of the scanning pass. After saline check , 100mL volume of iodinated contrast material (320 mg of iodine per milliliter), was administered through a 20-gauge cannula in an antecubital vein at a rate of 4.5mL/sec. through pressure injector followed by saline chase.

The scanning parameters were as follows

- 120kV,
- 200 mA (effective), and
- Section thickness of 2mm.

Scanning was begun when the contrast opacification of descending thoracic aorta reached 100 HU – determined by Automated bolus tracking technique. Images were reconstructed with an effective section thickness of 2mm and an increment of

1mm by using the smooth algorithm. All transverse source images were transferred to workstations for the preparation of reconstructions.

Sliding maximum intensity projections were obtained with coronal, and sagittal projections of each data set.

Whole-volume maximum intensity projections with segmentation of bone and vessel wall calcifications and Volume rendered images were obtained

All multi–detector row CT angiography examinations were performed by dedicated CT technologists. Postprocessing reconstructions were performed by dedicated CT technologists images interpreted by experienced radiologists

The images were analysed on the basis of transverse images , MIP & VR images – for stenosis, occlusion , calcification , plaque morphology and collaterals

Stenosis was graded as follows

Grade 1 - normal vessel or mild vessel irregularities (<10% luminal narrowing).

Grade 2 - moderate arterial stenosis (10%–49% luminal narrowing).

Grade 3 - severe arterial stenosis (50%–99% luminal narrowing).

Grade 4 - occlusion.

IMAGE ANALYSIS

The following vascular segments were analyzed independently for the presence of hemodynamically significant stenosis or occlusion , plaque morphology and collaterals.

- Infra-renal aorta,
- Common iliac artery
- External iliac artery
- Common femoral artery,
- Proximal superficial femoral artery
- Mid superficial femoral artery
- Distal superficial femoral artery
- Origin of deep femoral artery
- Popliteal artery
- Anterior tibial artery
- Posterior tibial artery

- Peroneal artery
- Dorsalis pedis .

Thus, for a patient with unilateral limb involvement, 13 segments were examined and in case of bilateral limb disease, 25 segments were examined.

RESULTS

The study involved 34 patients (32 men, 2 women). Of these patients, 28 were above 40 and 60 years of age. 3 patients had below knee amputation. Though 68 limbs, 835 individual arterial segments were evaluated using each modality but only 807 segments for available for comparison.

25 patients had atherosclerosis, 7 had TAO, while 1 had acute thrombosis due to trauma and 1 had cystic adventitial disease of popliteal artery.

2 had intermittent claudication (Fontaine's stage II), 7 had rest pain(Fontaine's stage III) , trophic changes , ulcers and gangrene were seen in 25 persons(Fontaine's stage IV).

18 were chronic smokers, 16 had diabetes and 25 had hypertension

STATISTICAL ANALYSIS

Results were tabulated and analyzed by two way contingency tables and Kappa statistics. Sensitivity , Specificity , Positive Predictive Value and Negative Predicitive Value were obtained .

AORTOILIAC REGION

INFRA RENAL AORTA

	CT positive	CT negative	Total
Doppler positive	1	0	1
Doppler negative	0	26	26
	1	26	27

Sensitivity : 100%

Specificity : 100%

PPV: 100%

NPV:100%

Analysis with Kappa statistics

COMMON ILIAC ARTERY

	CT positive	CT negative	Total
Doppler positive	7	0	7
Doppler negative	1	48	49
	8	48	56

Sensitivity :87.5%

Specificity : 100%

PPV: 100%

NPV: 97.96%

Analysis with Kappa statistics

EXTERNAL ILIAC ARTERY

	CT positive	CT negative	Total
Doppler positive	7	0	7
Doppler negative	1	54	55
	8	54	62

Sensitivity : 87.5 %

Specificity : 100 %

PPV: 100%

NPV: 98.18%

Analysis with Kappa statistics

FEMOROPOPLITEAL REGION

COMMON FEMORAL ARTERY

	CT positive	CT negative	Total
Doppler positive	9	0	9
Doppler negative	0	59	59
	9	59	68

Sensitivity : 100%

Specificity : 100%

PPV: 100%

NPV: 100%

Analysis with Kappa statistics

PROXIMAL PART OF PROFUNDA FEMORIS

	CT positive	CT negative	Total
Doppler positive	9	6	15
Doppler negative	0	53	53
	9	59	68

Sensitivity : 100% Specificity : 89.83%

PPV: 60% NPV: 100%

Analysis with Kappa statistics

PROXIMAL SUPERFICIAL FEMORAL ARTERY

	CT positive	CT negative	Total
Doppler positive	26	0	26
Doppler negative	0	42	42
	26	42	68

Sensitivity : 100% Specificity : 100%

PPV: 100% NPV:100%

Analysis with Kappa statistics

MIDDLE SUPERFICIAL FEMORAL ARTERY

	CT positive	CT negative	Total
Doppler positive	29	0	29
Doppler negative	0	39	39
	29	39	68

Senstivity : 100% Specificity : 100%

PPV: 100% NPV: 100%

Analysis with Kappa statistics

DISTAL SUPERFICIAL FEMORAL ARTERY

	CT positive	CT negative	Total
Doppler positive	35	2	37
Doppler negative	0	25	25
	35	27	62

Sensitivity :100% Specificity : 92.59%

PPV: 94.6% NPV: 100%

Analysis with Kappa statistics

POPLITEAL ARTERY

	CT positive	CT negative	Total
Doppler positive	43	2	45
Doppler negative	0	23	23
	43	25	68

Sensitivity : 100% Specificity :92%

PPV: 95.56% NPV: 100%

Analysis with Kappa statistics

INFRAPOPLITEAL REGION

ANTERIOR TIBIAL ARTERY

	CT positive	CT negative	Total
Doppler positive	9	7	16
Doppler negative	3	46	49
	12	50	65

Senstivity : 75% Specificity : 86.79%

PPV: 56.25% NPV: 93.88%

Analysis with Kappa statistics

POSTERIOR TIBIAL ARTERY

	CT positive	CT negative	Total
Doppler positive	14	6	20
Doppler negative	4	41	45
	18	47	65

Sensitivity :77.77%

Specificity : 87.23%

PPV: 70%

NPV: 91.11%

Analysis with Kappa statistics

PERONEAL ARTERY

	CT positive	CT negative	Total
Doppler positive	15	13	28
Doppler negative	5	32	37
	20	45	65

Sensitivity : 75 %

Specificity :71%

PPV: 53.57%

NPV: 86.48%

Analysis with Kappa statistics

DORSALIS PEDIS

	CT positive	CT negative	Total
Doppler positive	20	5	25
Doppler negative	7	33	40
	27	38	65

Sensitivity :74.07%

Specificity: 86.84%

PPV: 80%

NPV: 82.5%

Analysis with Kappa statistics

AORTO ILIAC REGION

Total number of segments	:	170
No of segments obscured by bowel gas	:	25
no of segments available for comparison	:	145

	CT positive	CT negative	
Doppler positive	14	0	14
Doppler negative	2	129	131
	16	129	145

Sensitivity : 87.5% Specificity : 100 %

PPV : 100% NPV: 98.6%

Analysis with Kappa statistics

FEMORO POPLITEAL REGION

Total number of segments = 402

	CT positive	CT negative	Total
Doppler positive	151	10	161
Doppler negative	0	241	241
	151	251	402

Sensitivity : 100% Specificity : 96.01%

PPV: 93.79% NPV: 100%

Analysis with Kappa statistics

INFRAPOPLITEAL REGION

Total number of segments = 260

	CT positive	CT negative	Total
Doppler positive	58	31	174
Doppler negative	19	152	86
	186	74	260

Sensitivity : 75.32% specificity :83.06%

PPV : 65.16% NPV:88.88%

Analysis with Kappa statistics

LOWER LIMB ARTERIAL SYSTEM

TOTAL NUMBER OF SEGMENTS ANALYSED : 807

	CT positive	CT negative	
Doppler positive	223	41	264
Doppler negative	21	522	543
	244	563	807

Sensitivity : 91.39 Specificity : 92.71

PPV: 84.47 NPV: 96.13

Analysis with Kappa

Table 3 showing sensitivity, specificity , PPV, NPV of Duplex ultrasound in the evaluation of lower limb arterial system

	SENSITIVITY%	SPECIFICITY%	PPV%	NPV%
Aortoiliac region	87.5	100	100	98.46
Femoropopliteal region	100	96.01	93.79	100
Infrapopliteal region	75.32	83.06	65.16	88.88
OVERALL SEGMENTS	91.39	92.71	84.47	96.13

Table 4 showing agreement between the two modalities –analysed with KAPPA STATISTICS

SEGMENT ANALYSED	AGREEMENT OF DUPLEX WITH CT ANGIOGRAPHY
Infrarenal aorta	Perfect (1.000)
Common iliac artery	Very good (0.923)
External iliac artery	Very good (0.924)
Common femoral artery	Perfect (1.000)
Superficial femoral artery- prox	Perfect (1.000)
Superficial femoral artery- mid	Perfect (1.000)
Superficial femoral artery-distal	Very good (0.934)
Proximal profunda femoris	Good (0.700)
Popliteal artery	Very good (0.936)
Anterior tibial artery	Moderate (0.547)
Posterior tibial artery	Good (0.629)
Peroneal artery	Moderate(0.415)
Dorsalis pedis	Good (0.616)

DISCUSSION

The study involved 34 patients out of whom 3 patients had below knee amputation.

Out of 34 patients, infra renal aorta was obscured by bowel gas in 7 patients. Out of those 27 segments assessed, 1 patient had significant stenosis and the rest had normal or hemodynamically insignificant stenosis. CT angiography confirmed the findings. The sensitivity, specificity, positive predictive value and negative predictive value of Doppler was 100% in evaluating infra renal aorta. The strength of agreement was perfect between Doppler and CT angiography when analysed with kappa statistics.

In common iliac arterial segment, out of 68 segments, 12 segments were not evaluated due to bowel gas. Of the evaluated 56 segments, Doppler was able to pick up 7 of the 8 hemodynamically significant stenosis. It missed significant stenosis in 1 patient who had a calcific plaque. False negativity in this patient could be due to over estimation of stenosis by CT angiography in arteries with calcific plaques. Because of this , the sensitivity of Doppler was reduced to 87.5% . However the strength of agreement was considered to be very good between Doppler and CT angiography when analysed with kappa statistics.

In external iliac arterial segment, out of 68 segments, 6 segments were obscured by bowel gas. In the remaining 62 segments, Doppler failed to detect hemodynamically significant stenosis in the same patient as that of common iliac artery, probably due to overestimation of the stenosis caused by calcific plaque by CT angiography. The sensitivity fell to 87.5% and the specificity was 100%. The strength of agreement was considered to be very good between Doppler and CT angiography when analysed with kappa statistics.

In the common femoral artery, Doppler was able to detect all the 9 hemodynamically significant stenosis with the resulting sensitivity and specificity of 100%. The strength of agreement was perfect between Doppler and CT angiography when analysed with kappa statistics.

In the proximal and middle superficial femoral artery, Doppler was able to detect all the 26 and 29 hemodynamically significant stenosis respectively with the resulting sensitivity and specificity of 100%.

In the distal superficial femoral artery, out of 68 segments , only 62 segments were available for comparison since in 6 patients distal SFA was not visualized – which is a blind spot for sonographers. In the evaluated patients , Doppler did not miss any hemodynamically significant stenosis – instead over estimated 2 segments with hemodynamically insignificant stenosis resulting in false positivity. These patients had long segment disease in the proximal and mid part of SFA which resulted in monophasic flow in the distal SFA which was mistaken for hemodynamically significant stenosis in the distal part[26].

Only the proximal part of Profunda femoris was evaluated in the study as the distal part and its branches were not accessible. Out of 68 segments evaluated, Doppler detected all hemodynamically significant stenosis. It also over estimated 6 segments with hemodynamically insignificant stenosis resulting in false positivity. These segments showed elevated peak systolic velocity due to compensatory increased flow through them to the distal leg when there is occlusion of SFA. As a result the specificity of Doppler in evaluating proximal profunda femoris was only 89.83% , while the sensitivity was 100%.

In the popliteal artery, Doppler did not miss any hemodynamically significant stenosis - instead over estimated 2 segments with hemodynamically insignificant stenosis in those patients who had long segment disease in the proximal and mid part of SFA with resultant monophasic flow in the distal SFA which was mistaken for hemodynamically significant stenosis[26]. The sensitivity and specificity of Doppler in evaluating popliteal artery was 100% and 92% respectively.

The infra popliteal vessels were evaluated only for the presence or absence of flow with Doppler which was compared to the presence of opacification or non opacification of those vessels with contrast in CT angiography.

Doppler was not able to find flow in 7 anterior tibial arterial segments, 6 posterior tibial arterial segments, 13 peroneal arterial segments and 5 dorsalis pedis which opacified with contrast in CT angiography. These patients had occlusion of femoropopliteal region with reformation of the infrapopliteal vessels at their mid or distal part and it was difficult to find the reformation of these vessels as there were many collateral vessels seen in the leg . Although major arteries are accompanied by venae commitants and not the collaterals it was still difficult to trace out the major vessels.

Interestingly , Doppler was able to pick up flow in those infrapopliteal vessels which were not opacified with contrast. In three patients with proximal significant stenosis, there was no opacification in the infrapopliteal vessels with the contrast , but Doppler was able to pick up monophasic flow . This could be because of different rates of crural vessel opacification, or inadequate opacification distal to an occlusion[28] in CT angiography. This implies that when Doppler is used in conjunction with CT angiography, the false positive occlusions of CT angiography could be minimized.

Thus , the sensitivity of Doppler in evaluating aortoiliac segments, femoropopliteal segments and infrapopliteal segments were 87.5%, 100% and 75.32% respectively and specificity in evaluating aortoiliac segments, femoropopliteal segments and infrapopliteal segments were 100%, 96.01% and 83.06% respectively if CT angiography was taken as gold standard. The agreement between the two modalities in the evaluation of aortoiliac region and femoropopliteal region was very good , and of infrapopliteal vessels is only moderate.

Earlier studies evaluating color Doppler imaging have shown varying degrees of sensitivity and specificity. We have observed a similar trend in our result [33] as shown in table 5.

Table 5 showing the results of previous Doppler studies in evaluating lower limb arterial system

	No of patient	Fontaine Stage	No of segment	Doppler positive		Doppler negative		Sensitivity	Specificity
				True positive	False	False	True		
Aly	90	90/9/1	3108	404	27	34	2643	92.2	99
Bergamini	44	NR	404	94	13	24	273	79.7	95.5
Hatsukami	29	NR	243	73	6	12	152	85.8	96.2
Linke	25	100/0/0	134	41	4	2	87	95.3	95.6
Sensier	76	88/0/12	469	214	26	28	201	88.4	88.5
El-kayali	44	NR	357	123	15	3	216	97.6	93.5
Legemate	61	80/16/3	918	179	30	33	676	84.4	95.8
This study	34	2/7/25	807	223	41	21	522	91.39	92.71

This study showed various advantages of Doppler over CT angiography .

When extensive calcifications are present in the vessel, the end product of CT angiography is of questionable diagnostic value [32] as it overstages the lesion. Doppler is able to demonstrate this overstaging of MDCT by showing that the calcific plaque which appears to have produced more than 50% stenosis has actually not resulted in hemodynamically significant stenosis .

Doppler is able to demonstrate flow in those infrapopliteal vessels where CT shows no opacification with contrast due to proximal significant stenosis .

It is also able to demonstrate the nature of plaque – whether calcific or soft plaque. Soft plaques were better demonstrated with ultrasound than with CT.

It is able to show the duration of occlusion – as acute thrombus distends the vessels while chronic occlusion narrows the vessel caliber. 1 patient had traumatic injury of right SFA and Doppler showed complete occlusion of the proximal and mid SFA with thrombus with distal monophasic flow. Although the occlusion was demonstrated in CT angiography the distension of the vessel with thrombus was not demonstrable in CT because of its lack of soft tissue resolution.

There is no hazard of radiation with Doppler , while the mean effective dose of radiation delivered to a patient in a single study with CT angiography is 12- 14 mSv.

Since no iodinated contrast is required, it is safely performed in patients with renal failure (these patients were excluded from the study in whom Doppler alone was done to evaluate the lowerlimb arteries)

Doppler could be performed in cases of emergencies like traumatic / iatrogenic injuries to rule out arterial obstruction at any time, while CT angiography is not easily available at all the time and is available only at apex institutions.

Doppler is also cost effective when compared to CT angiography.

CONCLUSION

Duplex Ultrasound provides high-resolution, precise anatomical and physiological information of the peripheral arteries. It is unlikely to misclassify a whole limb as “normal” and thus inappropriately screen out a patient from further investigation.[2]

Duplex Ultrasound was found to have a high negative predictive value and could exclude a significant lesion, thus helping to avoid other costly diagnostic modalities in a mildly symptomatic patient. It could determine the nature and extent of arterial disease based on which treatment can be planned, either endovascular or surgical.

It may also determine the significance of equivocal lesions identified by MDCT angiography. Combination of Duplex Ultrasound with MDCT angiography has better diagnostic accuracy.

Thus, Duplex Ultrasound is a safe, inexpensive, non-invasive, easily available diagnostic tool with high diagnostic accuracy and is indispensable in the investigation of peripheral arterial disease.

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ABBREVIATIONS

CTA - Computed Tomography angiography

DSA - Digital Substraction Angiography

DU - Duplex Ultrasound

MDCT - Multi Detector Computed Tomography

MRA - Magnetic Resonance Angiography

PAD - Peripheral Arterial Disease

PPV - Positive Predictive Value

NPV - Negative Predictive Value

PROFORMA– DOPPLER STUDY OF LOWER LIMB ARTERIES

NAME: AGE/ SEX :
STUDY NO : CLINICAL HISTORY:
RISK FACTORS:

	RIGHT				**LEFT**			
ARTERIAL SEGMENT	**VELOCITY**	**SPECTRAL PATTERN**	**PLAQUE MORPHOLOGY**	**% STENOSIS**	**VELOCITY**	**SPECTRAL PATTERN**	**PLAQUE MORPHOLOGY**	**% STENOSIS**
INFRA RENAL AORTA								
COMMON ILIAC ARTERY								
EXTERNAL ILIAC ARTERY								
CFA								
PROXIMAL PROFUNDA FEMORIS								
SFA-PROX								
SFA - MID								
SFA - DISTAL								
POPLITEAL								
ATA								
PTA								

PERONEAL ARTERY								
DORSALIS PEDIS								